

## PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference N.87992A SLS/tm		<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/GB2004/002748		International filing date (day/month/year) 25.06.2004		Priority date (day/month/year) 02.07.2003
International Patent Classification (IPC) or national classification and IPC A61M15/00				
Applicant MERIDICA LIMITED et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 15 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand  27.01.2005		Date of completion of this report  04.10.2005		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Valfort, C  Telephone No. +49 89 2399-2352		



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/002748

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-51 as originally filed

**Claims, Numbers**

1-53 as originally filed

**Drawings, Sheets**

1/20-20/20 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/002748

**Box No. IV Lack of unity of invention**

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
  - ☒ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
  - ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
  - ☐ the parts relating to claims Nos. .

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-8,10-11,23-30,32,34-39,41,43-47,50
	No: Claims	9,12-21,22,31,33,40,42,48,49,51-53
Inventive step (IS)	Yes: Claims	1-8,23-30,32,34-38,41,43-47,50
	No: Claims	9-21,22,31,33,39,40,42,48,49,51-53
Industrial applicability (IA)	Yes: Claims	1-53
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

**Re Item IV**

**Lack of unity of invention**

- 1 This Authority considers that there are 7 inventions covered by the claims indicated as follows:

1) Claims 1-8: A device for dispensing individual doses of powder from respective pockets of a carrier with a flow path downstream of each defined by walls unique for said pocket.

2) Claims 9-11: A device for dispensing individual doses of powder from respective pockets of a carrier with a first flow path communicating with the pocket and a second flow path bypassing said pocket.

3) Claims 12-21: A device for dispensing individual doses of powder from respective pockets of a pair of carriers.

4) Claims 22-32: A device for dispensing individual doses of powder from respective pockets of a carrier with a prodger/cam arrangement for rupturing the lidding sheet sealing the pockets.

5) Claims 33-38: A device for dispensing individual doses of powder from respective pockets of a carrier with priming member and intermittent-motion for interaction with the priming member.

6) Claims 39-47: A device for dispensing individual doses of powder from respective pockets of a carrier with a changeover component and an indexing mechanism.

7) Claims 48-53: A device for dispensing individual doses of powder from respective pockets of a carrier with a counting mechanism for counting the number of doses dispensed to the user.

- 1.1 The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

- 1.2 A device for dispensing individual doses of powder from respective pockets of a carrier with a support for a carrier having a plurality of pockets containing respective doses of powder, and a mouthpiece through which to inhale an airstream carrying a dose of powder is known from WO0185097 (D1) (see fig.1E and 5A). Independent claims 1,9,12,22,33,39 and 48 further define features of the device which relate to different problems: Claim 1 relates to the problem of insuring dose reproduction by avoiding aggregation of powder on the walls of the device, by providing a unique flowpath for each pocket. Claim 9 tries to improve medicament deposition by providing a second flowpath for bypassing the pocket. Claim 9 relates to a device with two disc carriers for different medicaments. Claim 22 defines a special arrangement for opening the pockets. Claim 33 relates to a priming member and intermittent-motion for interaction with the priming member. Claim 39 further defines a changeover component and an indexing mechanism. Claims 48 and 52 concentrate on a counting mechanism for the device. Therefore, claims 1,9,12,22,33,39 and 48 do not contain any common "special technical features" within the sense of Rule 13.2 PCT which define a contribution over WO0185097 (D1) and thus, the requirement of unity of the PCT are not fulfilled by the application.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

- 1 Reference is made to the following documents:

- D1: WO 01/85097 A (INNOVATIVE DEVICES LLC) 15 November 2001 (2001-11-15)
- D2: EP-A-1 106 196 (ATSUGI UNISIA CORP ; DOTT LTD COMPANY (JP)) 13 June 2001 (2001-06-13)
- D3: WO 02/094357 A (ASKING LARS ; ASTRAZENECA AB (SE); HARWIGSSON IAN (SE); JONSTROEMER MI) 28 November 2002 (2002-11-28)
- D4: US-A-4 811 731 (RAND PAUL K ET AL) 14 March 1989 (1989-03-14)
- D5: US-A-5 657 749 (COX PETER ERICH) 19 August 1997 (1997-08-19)
- D6: WO 01/17595 A (INNOVATA BIOMED LTD ; BRAITHWAITE PHILIP (GB)) 15 March 2001 (2001-03-15)
- D7: WO 03/015857 A (JENNINGS DOUGLAS IVAN ; EDE ANDREW JOHN (GB);

- MERIDICA LTD (GB)) 27 February 2003 (2003-02-27)
- D8: EP-A-0 469 814 (LILLY INDUSTRIES LTD) 5 February 1992 (1992-02-05)
- D9: WO 03/024514 A (ADVENT PHARMACEUTICALS PTY LTD ; ALLAN ROBERT DAVID (AU); PIKE GREGORY) 27 March 2003 (2003-03-27)
- D10: WO 02/24263 A (PIKE GREGORY CHARLES ; GLAXO GROUP LTD (GB))  
28 March 2002 (2002-03-28)
- D11: WO 95/11715 A (TENAX CORP) 4 May 1995 (1995-05-04)
- D12: US-B1-6 182 655 (EGGIMANN THOMAS ET AL) 6 February 2001 (2001-02-06)
- D13: GB-A-2 242 134 (GLAXO GROUP LTD) 25 September 1991 (1991-09-25)

**1) Claims 1-8: A device for dispensing individual doses of powder from respective pockets of a carrier with a flow path downstream of each defined by walls unique for said pocket.**

2. The subject-matter of claim 1 and 2 differs from the devices of D1 and D2 in that the walls for defining the individual respective first flow paths downstream of each respective pocket of a supported carrier and for connecting said pocket with the mouthpiece are part of the device itself and not part of the carrier, indeed the pocket and carrier are not part of the subject-matter claimed in claim 1 and 2.

2.1 The subject-matter of claim 1 and 2 is therefore novel over D1 and D2 (Article 33(2) PCT)

Note : nevertheless, the wording "forms an integral part of the individual first flow path" leads the reader to think that the said walls also cover the walls of the carrier and pocket itself (Article 6 PCT). Moreover the first flow path is inconsistent between claim 1 and 2. In claim 1 it is said to be defined entirely by respective walls unique to that individual first flow path, thus excluding that said flow path is also defined by part the pocket of the carrier, which is not coherent with the described embodiment where the part of the flow path is always going through the pocket of the carrier (Article 6 PCT).

2.2 In the prior art a single flow path in the device, apart from the blister itself, normally connects the pocket of a carrier to the mouthpiece see D1-D3. Therefore the subject-

matter of claims 1 and 2 also appears to fulfill the requirements of Article 33(3) PCT.

2.3 Claims 3-8 are dependent on claim 1 and 2 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

**2) Claims 9-11: A device for dispensing individual doses of powder from respective pockets of a carrier with a first flow path communicating with the pocket and a second flow path bypassing said pocket.**

5 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 9 is not novel in the sense of Article 33(2) PCT.

5.1 The document D5 discloses (the references in parentheses applying to this document):

A device for dispensing a dose of powder from a pocket of a carrier, the device including (fig.12):

a support for a carrier having a pocket containing a dose of powder (col.7 line 40-49, fig.12); and

a mouthpiece (fig.12) through which to inhale an airstream carrying a dose of powder; the device further including:

walls defining first (402 fig.12) and second flow paths (406, fig.12) communicating with the mouthpiece, the first flow path communicating with the pocket (fig.12) of the supported carrier and the second flow path (fig.12, col.7 lines 54-56) bypassing the pocket; wherein the walls defining the first flow path include, upstream of the pocket, a portion of relatively reduced cross-sectional area orientated so as to be directed towards the pocket and direct a relatively high velocity airstream into the pocket (col.7 lines 49-53 "venturi").

It is noted that claim 9 does not specify that the first flow path should have a smaller cross-sectional area than the second flow path, it is only said that the first flow has a portion of relatively reduced cross-sectional area, which is also the case in D5, see fig.12 the cross section of the passage 402 is reduced at the entrance of the blister 412.

Therefore, the subject-matter of claim 9 cannot be seen as novel in view of D5.

5.3 Claims 10 and 11 clearly state that the first passage has smaller cross-section than the

second one. Therefore said claims are novel over D5 (Article 33(2) PCT). Nevertheless, said slight constructional change in the subject-matter of claim 9 appears to come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of claim 10-11 lacks an inventive step (see also D3, fig.21 item 77).

**3) Claims 12-21: A device for dispensing individual doses of powder from respective pockets of a pair of carriers.**

- 6 The subject-matter of claim 12 is unclear within the sense of Article 6 PCT. The claim comprises a support for two disc shaped carriers, i.e. **suitable for** such carriers. The current wording of claim 12 leaves the reader in doubt as if the disc shaped carriers are part or not of the subject-matter claimed. The claim will be interpreted in the following way for the present report: the disc shaped carriers are not considered to be part of the subject-matter claimed, as the claim further defines features of the support.
- 7 Said lack of clarity notwithstanding, the present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 12 is not novel in the sense of Article 33(2) PCT.

**7.1 The document D6 discloses (the references in parentheses applying to this document):**

A device for dispensing individual doses of powder from respective pockets of a pair of carriers (page 4 line 25, fig.7), the device including:  
a support (106, fig.7) suitable for two disc shaped (see page 8 line 8 "a spool carrier magazine comprises a **disc**") carriers 101a and 101b, fig.7, (the following features are not part of the subject-matter claimed as the disc themselves are not part of the subject-matter of claim 12, see point 6. "each disc shaped carrier having at least one substantially planar first side surface having an annular array of cavities in which respective pockets are formed and a respective first lidding sheet sealed to the first side surface for enclosing the cavities". Anyway, apart from the lidding sheet, all the features of the disc shaped carriers are known from D6, see fig.7), wherein the supports are for rotatably supporting the carriers about a substantially common axis (see fig.7 and page 8 lines 13-31);



a mouthpiece (implicit, reference is made to an inhalation passage page 3 line 4, and said passage in DPI leads to a mouthpiece in order to carry the medicament to the user, see also page 4 line 25-31) through which to inhale an airstream carrying powder from the carriers;

a dispensing mechanism (rod 121, fig.7) for releasing into the airstream the powder of a respective pocket of a supported carrier; and

an indexing mechanism (107, fig.7, see page 13 lines 12-16) for rotating the carriers relative to the dispensing mechanism so as to enable powder to be released from different pockets.

Therefore, the subject-matter of claim 12 is not considered to be novel in view of the device of D6.

7.2 The subject-matter of dependent claims 13-21 is not considered to be novel either (Article 33(2) PCT). On page 8 lines 1-5 of D6, one can read that the push rod can actuated jointly, i.e therefore the two disc needs to be moved also jointly in order to present the medicament cavities in front of the push rods. Said same passage also envisages sequential delivery of the medicaments. Therefore the subject-matter of claims 13-19 does not appear to be novel in view of the device of D6. In D6 page 10 lines 1-6, it is explained that in one embodiment the first carrier is rotated from 360° and emptied before the second carrier is in turn actuated, therefore the subject-matter of claims 20-21 is not novel either (Article 33(2) PCT).

7.3 The subject-matter of claim 53 when combined with claim 12 is also not novel (Article 33(2) PCT) because said combination does not make clear that the carrier housed by the device effectively has all the features mentioned lines 19-22 of claim 12, and in particular that said carrier has a lidding sheet.

**4) Claims 22-32: A device for dispensing individual doses of powder from respective pockets of a carrier with a prodger/cam arrangement for rupturing the lidding sheet sealing the pockets.**

8 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 22,31 is not novel in the sense of Article 33(2) PCT.

8.1 The document D7 discloses (the references in parentheses applying to this document):

A device (fig.17) for dispensing individual doses of powder from respective pockets of a carrier, the device including:

a first support (page 16 line 18-21, indexing means for the rolled strip) for a first carrier (fig.5(d), page 16 lines 6-9, the device of fig.17 can be used for a strip having packs corresponding to fig.5(d)) having first and second side surfaces opposite each other, an array of cavities in which respective pockets are formed and a first lidding sheet sealed to the first side surface (it is noted that the carrier itself is not part of the subject-matter of claim 22, analogy to the clarity objection made under point 6 above);  
a first prodger member (72, fig.17, fig.22) moveable towards and away from the second side surface of a supported first carrier between a retracted and an extended position;  
a cam member (76) adjacent to and moveable generally parallel with the second side surface of a supported carrier between a rest position and a primed position; wherein the cam member has a first cam surface for engaging with the first prodger member such that movement of the cam member from the rest position to the primed position moves the prodger member from the retracted position to the extended position so as to press on the second side surface of a supported carrier and outwardly rupture the first lidding sheet of the supported first carrier (see page 16 lines 14-18, and page 17 lines 18 to page 19 line 8). Claim 31 merely described features of the carrier which is corresponding to the carrier of fig.5d and 22, and which is anyway not part of the subject-matter claimed. Moreover the prodger 72 in D7 will also be arranged to push the insert through the first lidding sheet (fig.17 and 22): therefore, the subject-matter of claims 22 and 31 is not considered to be novel in view of the device of D7 (Article 33(2) PCT). D8 also discloses an inhaler with cam (30, fig.1)/prodger (33, fig.1) arrangement (see fig.1, col.3 lines 9-21).

Even if one does not consider the arrangement 76/72 as a cam arrangement, it is clear for a skilled person that instead of a lever, a cam arrangement can be used in order to actuate the prodger 72. At least claim 22 in its form would lack an inventive step (Article 33(3) PCT).

9 The subject-matter of claim 23 differs from the device of D7 in that a second support for a second carrier, said first and second carriers having faces facing each other (fig.12 of the application), and second prodger are provided, so that movement of the cam

member moves the second prodger in order to rupture the lidding sheet of the second carrier.

9.1 The arrangement of claim 23 permits to use two carriers with different medicaments in a compact arrangement, because the two carriers are facing each other in use. Said arrangement is not derivable from the available prior art, and therefore the subject-matter of claims 23-29, appears to imply an inventive step (Article 33(3) PCT).

9.2 The subject-matter of claims 30 and 32 also does not appear to be derivable from the available prior art. In D7, the cam arrangement does not have any groove for excess of medicament, and the cam member is not deformable, due to the different construction of the device of fig.17 in D7.

**5) Claims 33-38: A device for dispensing individual doses of powder from respective pockets of a carrier with priming member and intermittent-motion for interaction with the priming member.**

10 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 33 is not novel in the sense of Article 33(2) PCT.

10.1 The document D9 discloses (the references in parentheses applying to this document):  
A device for dispensing individual doses of powder from respective pockets of a carrier, the device including:  
a chassis (fig.1);  
a first support (55, fig.4) mounted on the chassis for rotation about a central axis and for supporting a first carrier (fig.4) having cavities with respective pockets formed therein and arranged in a circular array centred on the central axis, the first support including an array of gear teeth (53, fig.6) centred on the central axis;  
a priming member (30, fig.1) mounted on the chassis for rotation about the central axis;  
and  
an intermittent-motion (18, fig.1) mounted on the chassis for interaction with the priming member and gear teeth of the first support such that rotation of the priming member from a first position to a second position causes rotation of the first support by a predetermined angle and rotation of the priming member back from the second position

to the first position causes no rotation of the first support (see page 5 line 14 to page 7 line 2, and especially page 5 line 34 to page 6 line 6). Therefore, the subject-matter of claim 33 is not considered to be novel in view of the device disclosed in D9 (Article 33(2) PCT).

10.2 The subject-matter of claim 33 does not appear to be novel in view of the device of D10 (see fig.1-4 and page 8 second §) and D11 (see fig.7B, 9, 11A-C and page 23 line 23 to page 24 line 8). It is stressed that the features of the so-called intermittent-motion mechanism are not as such defined in claim 33, therefore said feature is construed in a broad sense and any device (e.g as described in D9-D11) which insures at some stage a cooperation similar to the one claimed between the priming member and the gear teeth of the first support member is considered as an intermittent motion mechanism.

10.3 The subject-matter of claim 34 differs from the devices of D9-D11 in that the intermittent-motion mechanism is a Geneva wheel rotatably mounted on the chassis on an axis offset from the central axis. Said feature permits a flexible indexation of the cartridge within the inhaler in does not appear to be obvious in view of the available prior art. Therefore, the subject-matter of claim 34 and its dependent claims 35-38 appears to fulfill the requirements of Article 33(3) PCT.

**6) Claims 39-47: A device for dispensing individual doses of powder from respective pockets of a carrier with a changeover component and an indexing mechanism.**

11 The document D6 discloses (the references in parentheses applying to this document):

A device (figs.11-14) for dispensing individual doses of powder from respective pockets of a carrier, the device including:

first and second supports (lower part of 101a, fig.12, and upper one of 101b, fig.12) rotatable about a central axis and for supporting respective first and second carriers (rest of 101a and 101b, fig.12) having cavities with respective pockets formed therein and arranged in respective first and second circular arrays centred on the central axis (it is noted that the carriers themselves are not part of the subject-matter claimed, see point 6);

a changeover component (111a, fig.11) located between the first and second supports,

the first support having a first feature (cutaway portion in 101a, see fig.12 and 14) for engaging with the changeover component and the second support having a second feature (cutaway portion in 101b, see fig.12 and 13) for engaging with the changeover component; and

an indexing mechanism (plate 106, fig.12 and page 8 lines 13-16 ) arranged to rotate each of the first and second supports; wherein the indexing mechanism is arranged to rotate the first support while the first feature engages the changeover component, the changeover component being arranged to then engage the second feature so as to rotate the second support to a position from which the indexing mechanism is arranged to rotate the second support (see page 10 lines 1-6, once the first carrier has been emptied, the member or changeover component 111a moves to the position in which the second support and carrier are moved).

11.1 The subject-matter of claim 39 thus differs from the device of D6 in that it is not the first support which moves the changeover component 111a but the component 111a which moves itself to track 124 (see fig.14), when it arrives at the break in the track 125. Nevertheless, it still can be said that the changeover component 111a rotates the second support to a position from which the indexing mechanism is arranged to rotate the second support (e.g at least after the first move of 111a, the second support is - again - in such a position). The subject-matter of claim 39 is consequently novel over D6 (Article 33(2) PCT).

11.2 It is not clear at the moment which technical effect is derivable or which problem is solved by said feature, in view of the prior art D6. Therefore, the subject-matter of claim 39 does not appear to involve an inventive step within the sense of Article 33(3) PCT.

11.3 The subject-matter of claims 40 and 42 does not appear to be inventive either (see figs.11-14 and the passages already cited under point 11.1).

11.4 The subject-matter of claims 41,43-47 does not appear to be rendered obvious by the available documents. D6 does not disclose supports having gear teeth, nor a Geneva wheel arrangement or a dose counting system. Therefore, the subject-matter of claims 41,43-47 appears to fulfill the requirements of Article 33(3) PCT.

**7) Claims 48-53: A device for dispensing individual doses of powder from respective pockets of a carrier with a counting mechanism for counting the number of doses dispensed to the user.**

12 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 48,51 (when dependent on claim 48),52-53 is not novel in the sense of Article 33(2) PCT.

12.1 The document D12 discloses (the references in parentheses applying to this document):

A device for dispensing individual doses of powder from respective pockets of a carrier (see col.18 lines 66 to col.19 line 4), the device including:

an indexing mechanism (implicit, an embodiment with blisters on a tape needs a kind of indexing system in order to present the blisters with the inhalation passage and the means for opening the blisters, see e.g. D13 fig.16) for indexing the carrier between respective pockets;

a first counter ring (see fig.16, 701 and col.13 line 2) having an indication of unit counts on a first display surface, the first counter ring being rotatable about a counter axis;  
a second counter ring (780, fig.16, col.13 line 3) having an indication of tens counts on a second display surface, the second counter ring being rotatable about the counter axis;  
and

an intermittent-motion mechanism for driving the second counter ring from the first counter ring and rotating the second counter ring between consecutive tens counts when the first counter ring rotates between two predetermined consecutive unit counts, the first counter ring being driven with the indexing mechanism (in col.13 line 44-50, it is explained that the counter is incremented by closing the protective cap, it is clear for the skilled person that said action would also act with respect to the indexing of the tape in the blister tape embodiment, like in document D13).

It is stressed that the references made to D13 in the paragraph above are only there to strengthen the argumentation why said feature can be considered as implicit for a skilled person reading the disclosure of D12. Moreover in D12, the counter rings are also partially positioned one within the other (see fig.16a and 16b, even if the display surface are not on the same side as in the application - see fig.20 of the application -, the display

surface are as such not yet specified in claims 48,51,52-53).

Therefore the subject-matter of claims 48,51 (when dependent on claim 48), 52-53 is not novel in view of document D12.

- 12.2 The scope of "Geneva mechanism" is unclear within the sense of Article 6 PCT, as the features implied by said wording cannot be determined. Therefore the subject-matter of claim 49 lacks clarity, said lack of clarity notwithstanding, the claim is not considered to be novel (Article 33(2) PCT) as it does not clearly further restrict the scope of claim 48.
13. The subject-matter of claims 50 and 51 (when dependent on claim 50) does not appear to be derivable from the available prior art, as D12 nor D13 do disclose a Geneva wheel in order to engage the second counter ring. Thus the subject-matter of claims 50-51 appears to fulfill the requirements of Article 33(3) PCT.
14. The closest prior arts (D1, D5, D6, D7, D9, D12) of the different inventions have not been identified as required by Rule 5(a)(ii) PCT. Furthermore, the independent claims are not in the two-part form as required by Rule 6.3(b) PCT. Moreover, the claims do not include reference signs in parentheses as required by Rule 6.2(b) PCT.